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I. INTRODUCTION

Defendants Teva Pharmaceuticals USA, Inc. (“Teva”), Apotex Corp. and Apotex Inc. (“Apotex”) (collectively, “Defendants”) have presented in their post-trial Proposed Findings of Fact and Conclusions of Law entirely new main invalidity and unenforceability arguments that they did not raise in the parties’ stipulated Pretrial Order. Defendants’ new invalidity argument concerns Defendants’ heretofore unexplained selection of the so-called “2,3-dichloro propoxy compound” as one of Defendants’ lead compounds in support of their assertion that the claimed subject matter of the patent-in-suit would have been obvious. Defendants’ new unenforceability argument concerns the alleged withholding of internal anti-apomorphine stereotypy data on aripiprazole and the “2,3-dichloro propoxy compound” by Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”) during reexamination of the patent-in-suit, Otsuka’s U.S. Patent No. 5,006,528 (“the ’528 patent”).

Defendants did not identify either of these new arguments in the stipulated Pretrial Order governing trial of this case, despite that Magistrate Judge Goodman gave Defendants a second chance to modify their pretrial submission substantially after they initially had failed to provide their factual and legal arguments in sufficient detail. Nor did Defendants’ experts address these arguments during Defendants’ case-in-chief, thereby depriving Otsuka the opportunity to respond at trial. Instead, Defendants presented these arguments for the very first time in their post-trial briefing. Moreover, in raising these new arguments, Defendants have failed to make a showing, or even make any suggestion, that any prejudice or injustice would result if Defendants were not permitted to modify the Pretrial Order and make these new arguments after trial. Because Judge Goodman explicitly and repeatedly stated in the Pretrial Order that the terms of the Order shall not be modified absent a showing of manifest injustice, as expressly required by Fed. R. Civ. P. 16(e), Otsuka respectfully submits that an order striking Defendants’ new

arguments is warranted. Otsuka therefore respectfully moves to strike the new arguments that Defendants raised for the first time in their Proposed Findings of Fact and Conclusions of Law.

II. ARGUMENT

A. Legal Standards

Federal Rule of Civil Procedure 16(e) governs the final Pretrial Order and states that the Order may be modified “only to prevent manifest injustice.” Fed. R. Civ. P. 16(e). Consistent with this mandate of Rule 16(e), the Third Circuit has repeatedly held that parties are not permitted to raise arguments for the first time during or after trial when these arguments were not identified in the Pretrial Order. *See, e.g., Mannarino v. Morgan Township*, 64 Fed. Appx. 844, 846-47 (3d Cir. 2003) (unpublished) (affirming district court’s refusal to allow defendants to raise issue for first time in closing arguments, stating “[b]ecause the ... argument was not identified in the Pretrial Order, plaintiffs did not have a meaningful opportunity to address its merits at trial”); *Petree v. Victor Fluid Power, Inc.*, 831 F.2d 1191, 1194 (3d Cir. 1987) (“The finality of the pretrial order contributes substantially to the orderly and efficient trial of a case ... The plaintiff has offered no compelling reason why the proposed theory of liability was not disclosed at the pretrial conference. Therefore, we find no abuse of discretion in the district court’s refusal to grant the plaintiff’s eleventh hour motion to amend the pretrial order.”). Defendant Teva is well aware of Rule 16(e)’s prohibition against such new arguments, having already been rebuked in another case in the District of New Jersey for attempting to interpose for the first time in its post-trial briefing new arguments not raised in the Pretrial Order. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 482 F. Supp. 2d 390, 475 (D.N.J. 2007), *rev’d in part on other grounds*, 518 F.3d 1353, 1359 n.5 (Fed. Cir. 2008) (“We need not address the propriety of the district court’s refusal to consider this issue[.]”).

Accordingly, and for the reasons discussed below, the Court should strike from Defendants' Proposed Findings of Fact and Conclusions of Law the new arguments that Defendants did not raise in the stipulated Pretrial Order.

B. Defendants' New Post-Trial Arguments, Which Are Presented Without a Showing of Manifest Injustice, Should Be Stricken

Pursuant to this Court's Eighth Pretrial Scheduling Order dated December 14, 2009, the parties were ordered to exchange initial drafts of the Pretrial Order on February 1, 2010. (D.I. 300 at 1.) Defendants provided their initial draft to Otsuka on February 1, 2010, but this draft did not present Defendants' factual and legal arguments in sufficient detail. (*See* Ex. 1¹.) Accordingly, Otsuka sought relief from Magistrate Judge Goodman. (*See* Ex. 1; Ex. 2.) As set forth in the Ninth Pretrial Scheduling Order, Judge Goodman ordered Defendants to provide a revised draft of the Pretrial Order to Otsuka by April 16, 2010. (D.I. 309 at 1.) Judge Goodman further ordered the parties to submit their final version of the Pretrial Order to the Court on May 24, 2010. (*Id.* at 2.)

After the parties submitted the Pretrial Order on May 24, 2010, Judge Goodman held a final pretrial conference on June 1, 2010. (D.I. 312 at 1.) During the final pretrial conference, Judge Goodman informed the parties that once the Court approved the parties' final Pretrial Order, no further amendments would be permitted absent a showing of manifest injustice. Judge Goodman therefore permitted the parties to revise the Pretrial Order and resubmit it to the Court no later than June 25, 2010. (*Id.*)

On the signature page of the final version of each draft of the Pretrial Order that the parties exchanged, as well as the final version of the Pretrial Order that the parties signed and

¹ "Ex. ____" refers to the exhibits attached to the Declaration of Justin J. Hasford, filed herewith.

submitted to the Court on June 25, 2010 for approval, the parties included the following statement:

**AMENDMENTS TO THIS PRETRIAL ORDER WILL NOT
BE PERMITTED UNLESS THE COURT DETERMINES
THAT MANIFEST INJUSTICE WOULD RESULT IF THE
AMENDMENT IS DISALLOWED.**

(*See, e.g.*, Ex. 1; D.I. 328 at 169 (capitalization and bold in original).) Judge Goodman approved the parties' final Pretrial Order on July 14, 2010, specifically annotating the signed Order in three additional locations to make completely clear that any amendment to the Pretrial Order would be subject to a showing of manifest injustice. (*Id.* at 70, 132, 135.)

In Defendants' statement of contested factual and legal issues in the Pretrial Order, Defendants included various allegations that the claims of the patent-in-suit would have been obvious to a skilled artisan and the patent-in-suit is unenforceable based on purported inequitable conduct before the U.S. Patent and Trademark Office. (D.I. 328 at 70-131, 164.) Defendants did not, however, include in either their initial draft or the final version of the Pretrial Order any obviousness argument relying on the "2,3-dichloro propoxy compound" as a lead compound, or any inequitable conduct argument concerning the alleged withholding of internal stereotypy data on aripiprazole and the "2,3-dichloro propoxy compound" by Otsuka. (*See* Ex. 1; D.I. 328.) Nor did Defendants raise any of these issues during their case-in-chief at trial. (*See* D.I. 345-47, 349, 351-52, 354-56, 362, 365-67, 370.) Defendants' argument concerning the alleged withholding of the internal stereotypy data was raised for the first time during the cross examination of Otsuka's witness Dr. Oshiro, who did not testify until after the completion of testimony by all of the technical expert witnesses. Thus, Otsuka's technical experts were not able to address this new argument.

The only issue Defendants identified before trial with respect to the “2,3-dichloro propoxy compound” concerned Defendants’ narrow argument that the “2,3-dichloro propoxy compound” and the so-called “unsubstituted butoxy” compound allegedly “bracket” aripiprazole. (*See* Ex. 3 at 19.) Defendants did **not** include this argument in the Pretrial Order (*see* D.I. 328) but instead raised it in their trial brief, and only in the context of repeatedly and incorrectly asserting that the U.S. Patent Office rejected the claims of the ’528 patent over the “2,3-dichloro propoxy compound” during reexamination (*see* Ex. 3 at 4, 19, 38). In fact, as the ’528 patent reexamination file history makes clear, the Patent Office never rejected any claims of the ’528 patent over the “2,3-dichloro propoxy compound.” (*See* DTX-121.) Given that Defendants’ “bracketing” argument concerning the “2,3-dichloro propoxy compound” was premised on a blatant error, Otsuka had no reason to believe that the “2,3-dichloro propoxy compound” would now become Defendants’ primary lead compound for their obviousness allegations in their post-trial briefing. As such, this narrow and inaccurately premised assertion should not give Defendants a basis to include entirely new, broad obviousness allegations based on the “2,3-dichloro propoxy compound” for the first time in their post-trial briefing.

Moreover, Defendants’ new arguments are not simply additional details offered in support of arguments previously outlined in the Pretrial Order. Rather, they are now Defendants’ **main** arguments in support of their obviousness and unenforceability defenses, and they are undeniably distinct from what Defendants had previously identified as their main arguments in the Pretrial Order. Defendants’ presentation of these new invalidity and unenforceability arguments therefore violates Rule 16(e) as well as the terms of the stipulated Pretrial Order, including Judge Goodman’s repeated admonitions that any amendment to the Pretrial Order would be subject to the requisite showing of manifest injustice. (D.I. 328 at 70, 132, 135, 169.)

Defendants have made no such showing and have not even asserted that *any* prejudice or injustice would result if the Court were to deny Defendants' eleventh-hour attempt to modify the Pretrial Order and interpose new arguments after trial. Rather, after eschewing their *two* opportunities to raise these arguments in the Pretrial Order, Defendants simply incorporated these new arguments into their Proposed Findings of Fact and Conclusions of Law without seeking leave of Court. Defendants' new arguments accordingly should be stricken from their post-trial briefing.² See, e.g., *Mannarino*, 64 Fed. Appx. at 847; *Petree*, 831 F.2d at 1194; *Pfizer*, 482 F. Supp. 2d at 475.

C. Defendants' Likely Argument That Otsuka Is Not Prejudiced Is Neither Accurate Nor Apposite

Notwithstanding this clear legal authority and the plain terms and conditions of the stipulated Pretrial Order, Otsuka anticipates that Defendants will contend that Otsuka is not prejudiced by Defendants' new arguments in their post-trial briefing. Defendants are wrong. Indeed, Otsuka has been prejudiced substantially by being forced to respond to arguments Defendants have raised for the first time either later in the trial proceedings or after the completion of trial, thereby being deprived of a meaningful opportunity to address the merits of these arguments at trial. See, e.g., *Mannarino*, 64 Fed. Appx. at 847 ("Because the statute of limitations argument was not identified in the Pretrial Order, plaintiffs did not have a meaningful opportunity to address its merits at trial. We therefore agree with plaintiffs that allowing defendants to raise the defense on appeal would constitute unfair prejudice and, accordingly, we affirm the District Court on this issue.").

² Otsuka strongly disagrees with Defendants' new invalidity and unenforceability arguments and has addressed each of these arguments in Otsuka's Proposed Findings of Fact and Conclusions of Law.

Moreover, Defendants' contention that Otsuka has suffered no prejudice applies the wrong legal standard. As discussed above, the legal standard set forth in Rule 16(e), and stated no less than four times in the stipulated Pretrial Order, disallows any amendment to the Pretrial Order unless the party seeking to amend the Order shows that manifest injustice would result if the amendment is not permitted. (*See supra* Section II.B.) Because Defendants have not even suggested, let alone established, that the Pretrial Order should be amended to prevent injustice to Defendants, the Court should strike Defendants' new arguments from their post-trial briefing. *See, e.g., Petree*, 831 F.2d at 1194 ("The plaintiff argues that, for various reasons, no prejudice to the defendant would result from permitting the proposed amendment. However, this argument is inapposite because the standard is, conversely, that amendment *shall* be permitted only to *prevent* injustice.") (emphasis in original).

III. CONCLUSION

For the reasons discussed above, Otsuka respectfully requests that the Court strike from Defendants' Proposed Findings of Fact and Conclusions of Law the new arguments that Defendants did not raise in the final Pretrial Order.

Dated: October 12, 2010

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